





July 10, 2002

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Department of Health and Human Services  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

CITIZEN PETITION

A. Action Requested

CollaGenex Pharmaceuticals, Inc. ("CollaGenex") submits this petition under Sections 505(j)(2)(A) and 505(j)(7)(C) of the Food, Drug, and Cosmetic Act ("FDCA") and 21 C.F.R. §§ 10.30, 314.122, 314.127(a)(11), and 314.161(a)(1) to request that, because Periostat (doxycycline hyclate) 20 mg capsules ("the capsules") were voluntarily withdrawn from sale in the United States in 2001, the Commissioner of Food and Drugs refuse to approve any ANDA for a generic version of the capsules until FDA determines that they were not withdrawn for reasons of safety or effectiveness. CollaGenex also asks that the Commissioner refuse to receive or approve any abbreviated new drug application ("ANDA") for a generic version of the capsules that is not accompanied by a petition seeking a determination about whether they were withdrawn for safety or effectiveness reasons, and rescind any previous receipt or approval of any ANDA which refers to the capsules as the listed drug.

CollaGenex further asks the Commissioner to immediately move the capsules to the "Discontinued Drug Product List" in Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book," and to publish a Federal Register notice announcing the withdrawal of the NDA for the capsules. Both actions should take effect retroactive to the date of the capsules' withdrawal from sale.

CollaGenex also is filing a Petition for Stay of Action asking the Commissioner to stay the receipt or approval of any ANDAs until final resolution of the issues raised in this Citizen Petition.

B. Statement of Grounds

FDA approved Periostat capsules in September 1998. The agency approved Periostat tablets in February 2001.

CollaGenex voluntarily stopped the distribution and marketing of Periostat capsules in August 2001. Since then, it has sold only Periostat tablets. In September 2001, it wrote to the agency to withdraw the new drug application (NDA) for Periostat capsules in accordance with 21 C.F.R. § 314.150(c). A copy of the letter is attached as Exhibit A. CollaGenex also filed

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under 21 C.F.R. § 314.81(b)(3)(iii) the required FDA Form 2657 regarding the capsules' withdrawal from sale. A copy is attached as Exhibit B. In short, the capsules were voluntarily withdrawn from sale, and CollaGenex submitted to FDA the required paperwork for voluntary withdrawals from sale.

FDA did not, however, publish a notice in the Federal Register announcing the withdrawal of the NDA for Periostat capsules, as it is required to do under 21 C.F.R. § 314.152. Nor did it move the capsules to the "Discontinued Drug Product List," which the Orange Book states is the appropriate list for "approved products that ... have been discontinued from marketing[.]" Orange Book, Section 2.1, p. 2-1. Thus, would-be ANDA applicants have been unable to learn from the usual public sources that the capsules were voluntarily withdrawn from sale.

FDA's regulations require an ANDA that "refers to...a listed drug that has been voluntarily withdrawn from sale in the United States" to be accompanied by a petition requesting a determination that it was not withdrawn for safety or effectiveness reasons (a "§ 314.122 petition"). 21 C.F.R. § 314.122(a). Because the capsules were voluntarily withdrawn from sale in 2001, FDA cannot receive or approve an ANDA that refers to them unless the ANDA is accompanied by a § 314.122 petition.

CollaGenex believes that at least one ANDA has been submitted for a generic version of the capsules. Specifically, it has learned that West-Ward Pharmaceutical Corporation has asked to add its version of the capsules to the New Jersey Drug Utilization Council's list of approved generic substitutions, List of Interchangeable Drug Products, August 2002 Proposed Amendments, available at [www.state.nj.us/health/mgmt/rulepro0802a.htm](http://www.state.nj.us/health/mgmt/rulepro0802a.htm), a step generic drug companies usually take only after submission of an ANDA. Although 21 C.F.R. §§ 10.25 and 10.30 require § 314.122 petitions to be publicly available, CollaGenex has found no such petition in FDA's dockets. It therefore believes that any ANDAs for the capsules were not accompanied by the required § 314.122 petitions.

If sponsors have submitted ANDAs not accompanied by § 314.122 petitions, it may well be due to their unawareness of the need for a § 314.122 petition, because of FDA's failure to withdraw the NDA for Periostat capsules and move the capsules to the Orange Book's discontinued list. FDA's mistakes cannot, however, justify allowing ANDAs referring to Periostat to be received or approved without an accompanying § 314.122 petition. Somerset Pharmaceuticals, Inc. v. Shalala, 973 F. Supp. 443 (D. Del. 1997).

FDA should now take all steps necessary to rectify the situation:

1. FDA should refuse to approve any ANDA for a generic version of the capsules until FDA determines that they were not withdrawn for reasons of safety or effectiveness.
2. FDA should refuse to receive or approve any ANDA that is not accompanied by a § 314.122 petition, and rescind any previous receipt or approval of any ANDA that refers to the capsules as the listed drug.
3. FDA should immediately move the capsules to the Discontinued Drug Product List in the Orange Book and publish a Federal Register notice withdrawing the NDA for the

capsules, both of which should be retroactive to the date of the capsules' voluntary withdrawal from sale.

C. Environmental Impact

The action requested qualifies for categorical exclusion from the requirement of issuance of an environmental assessment under 21 C.F.R. § 25.31(a). CollaGenex does not believe that any environmental impact will result from the granting of this petition.

D. Economic Impact

In accordance with 21 C.F.R. § 10.30(b), CollaGenex will provide data concerning the economic impact of the action sought if requested by the Commissioner.

E. Certification

CollaGenex certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to CollaGenex that are unfavorable to the petition.

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